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10/580,563

05/26/2006

Susanne Matheus

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT

PAPER NUMBER

1656

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,563	<b>Applicant(s)</b> MATHEUS ET AL.	
	<b>Examiner</b> SUZANNE M. NOAKES	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/26/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-15 in the reply filed on 24 March 2008 is acknowledged. The traversal is on the ground(s) that Shenoy et al. do not in fact teach anti-EGFR crystals or how to make them. It is asserted that the disclosure merely lists anti-EGFR antibodies under examples of anti-growth factor antibodies (paragraphs 0324) and that no crystals have in fact ever been formed or taught how to make. Upon further reconsideration, Applicants arguments are convincing. Therefor, claims 16-18 will be rejoined and examined. It is noted, however, that these claims are interpreted as methods of making a pharmaceutical medicament with the product of claim 1.

### ***Status of the Claims***

2. Applicants have cancelled claims 4 and 5. Thus, claims 1-3 and 6-18 are subject to examination on the merits.

### ***Priority***

3. It is noted that Applicants claim benefit to a foreign priority document, DE 103 55 904.3. However, said document is not in English and thus an English translation will be required to overcome any intervening art which falls between the foreign priority date and the PCT filing date.

***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 26 May 2006 has been considered by the examiner. It is noted that Applicants have not submitted to this Office any foreign or non-patent literature references cited on said IDS and thus these have not been considered. See initialed and signed PTO-1449.

***Specification***

5. The disclosure is objected to because of the following informalities: The first line of the specification should refer to the application to which the instant application claims benefit to (e.g. PCTEP04/012837, filed 12 November 2004). See 37 C.F.R. 1.78 and MPEP 201.11.

6. The specification is further objected to because it is suggested that a Detailed Description of the Invention heading be inserted into the specification after the Summary of the Invention. See MPEP 608.01(g).

Appropriate correction is required.

***Claim Objections***

7. Claims 1-3 and 6-18 are objected to because of the following informalities: In the first instance where an acronym is used in an independent claim, said acronym should be spelled out in full, followed by the abbreviation in parenthesis. Thus, in claims 1 and 9, "anti-EGFR" should be spelled out as 'anti-epidermal growth factor receptor'.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> paragraph and 35 USC § 101***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 16-18 provides for the use of a solid form of an anti-EGFR antibody according to claim 1 for the preparation of a medicine, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

11. Claims 16-18 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See also MPEP 2173.05(q).

12. Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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13. It is noted that claims 13-15 are dependent upon claim 1 which recites: "Solid crystal form of an anti-EGFR antibody.....". Claim 13, however, recites a preparation comprising at least one solid form according to claim 1 in precipitated non-crystalline, precipitated crystalline or insoluble or suspended form. However, claim 1 already requires that the solid form is crystalline. Thus, claims 13-15 minimally lack antecedent basis and are also confusing and indefinite. The claims could be modified to recite, however, "further comprising" and then recite the listed forms of claim 13, which would remedy the confusion.

***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> paragraph***

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement:**

15. Claims 1-3 and 6-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that anti-EGFR antibodies are required to practice the claimed invention. As required elements, ALL anti-EGFR antibodies encompassed by the claims must be known and readily available to the public or obtainable by a repeatable

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method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Applicant is reminded that the following and should amend the specification accordingly.

The current address of the ATCC is as follows:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA  
20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the

case the statement need not be verified. See MPEP 1.804(b).

In the instant application, it is noted that the only anti-EGFR antibody used in the specification to make solid crystal anti-EGFR antibodies is Erbitux<sup>TM</sup>, also known as MabC225 or cetuximab. While this antibody is publicly available for purchase, the restrictions and assurances made by the owners of this product, which is directed to US patent 6217866 and US patent 5558864 (both cited on the instant IDS), does not reside in the hands of the instant Applicants. As such, Applicants are required to indicate how the assurances and restrictions with regard to the public availability of the anti-EGFR antibodies, especially that of Erbitux<sup>TM</sup>, as required and set forth above will be irrevocably removed should the instant application be allowable and issue as a United States patent.

Scope of Enablement:

Should the above deposit requirement and/or removal of restrictions along with the assurances are satisfied, the following 112 1st paragraph rejections apply.

16. Claims 1-3 and 6-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for solid crystals of whole murine humanized monoclonal antibodies of Erbitux/MabC225/cetuximab Erbitux/MabC225/Cetuximab produced by very specific crystallization methods and conditions of Example 2 and 3 only, does not reasonably provide enablement for crystals of any or all anti-EGFR antibodies above or beyond what is described in these examples. The specification does not enable any person skilled in the art to which it pertains, or with which it is most



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nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to crystals of anti-EGFR antibodies and methods of making therefor. However, the specification *only* sufficiently describes crystals that have been produced by the specific examples described in Examples 2 and 3 which discloses using Erbitux™ at a concentration of 20mg/ml in either 10 mM phosphate buffer at pH 8.0 or 10 mM citrate buffer at pH 5.5, adding either 10 mM phosphate buffer pH 8.0 to the phosphate protein solution or 10 mM citrate buffer pH 5.5 to the citrate protein solutions, respectively, and finally adding saturated ammonium sulfate in 10 mM phosphate buffer pH 8.0 to the phosphate protein-buffer solution or 50% v/v ethanol in 10 mM citrate buffer pH 5.5 to the citrate protein-buffer solution, respectively (it is noted that all additions are phosphate buffers to phosphate buffers and citrate buffers to citrate buffers/salts) and shaking this solution by hand for an undisclosed period of time at either room temperature or 4°C. It is presumed that the anti-EGFR antibody humanized monoclonal antibody Erbitux™ used in the crystallization procedures of Examples 2 and 3 is commercially purchased but this is not disclosed. Beyond this scope, however, the specification and claims are not sufficiently enabled for a skilled artisan not to have to endure a considerable amount of undue experimentation because: a) the specification does not disclose crystallization of any other anti-EGFR antibodies at all and b) there is considerably unpredictability in crystallizing any protein or antibody to begin with. Furthermore, the specification states that this is the first time any anti-EGFR antibody has been crystallized, especially, Erbitux/MabC225/Cetuximab

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and thus there is no prior art teachings a skilled artisan can rely upon for help or guidance beyond the prior art which falls between the foreign priority date and the effective filing date of the instant PCT (see 35 USC 102(e) rejection below). Thus, a skilled artisan, in order to achieve the full scope of that which is being claimed, would be required to practice undue experimentation. In this case, the burden is seen as undue when the Wands analysis is considered.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

In the instant case, the quantity of experimentation would be considerable because the smallest change in **any** parameter in crystallizing a protein/antibody can have enormous consequences. Thus, it is not enough to have the crystallization conditions of a related/similar protein/antibody or 'native' protein/antibody. Rather, what would be required is precise instruction about how to make each and every anti-EGFR antibody crystal in order to avoid undue experimentation, and this includes precise instruction of how the protein/antibody was exactly produced and exactly purified, which include the noted assurances of public availability as noted above. However, beyond that which is described in Examples 2 and 3, there is no adequate direction or guidance in the specification of how a skilled artisan might achieve crystal growth of any other anti-EGFR antibody in any other conditions or with any other crystallization techniques (e.g. microbatch, macrobatch, sitting drop, capillary liquid-liquid diffusion etc.). The nature of the invention and of the prior art suggests that crystallizing proteins and antibodies is an extremely tenuous science; what works for one protein or antibody does not necessarily for another, and what works for one native protein or antibody does not necessarily work for a mutant or fragment even though they essentially contain the same protein/antibody that has already been crystallized. It is noted that Applicants attempted to crystallize Erbitux<sup>TM</sup> using a commercially available crystallization grid matrix screen, Crystal Wizard I, and were only able to successfully produce salt crystals (see Example 8). Thus, this also lends weight to the fact that crystallization of proteins and antibodies is not straight forward and is unpredictable at best. Specific overexpression protocols, precise protein purification protocols and exact crystallization

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conditions (e.g. temperature, buffer, salt, protein concentration etc.) are needed for each protein and/or antibody (see Weber, Overview of Crystallization Methods. Methods in Enzymology, 1997, Vol. 276, pp. 13-22).

The nature of the invention and of the prior art suggests that crystallizing proteins is an extremely tenuous science; what works for one protein does not necessarily for another, and what works for one native protein does not necessarily work for a mutant or a protein complex even though they contain the same protein that has already been crystallized. Specific crystallization conditions (e.g. temperature, buffer, salt, protein concentration etc.) are needed for each protein (or protein complex). McPherson (Eur. J. Biochem. 1990, 189:1-23) outlines 25 different parameters which do or could affect the crystallization of any protein (see Table 2, p. 13). It is stated (p. 13, 2<sup>nd</sup> column,

*Factors influencing protein crystal growth*):

“Table 2 lists physical, chemical and biological variables that may influence to a greater or lesser extent the crystallization of proteins. The difficulty in properly arriving at a just assignment of importance for each factor is substantial for several reasons. Every protein is different in its properties and, surprisingly perhaps, this applies even to proteins that differ by no more than one or just a few amino acids. There are even cases where the identical protein prepared by different procedures or at different times may show significant variations. In addition, each factor may differ considerably in importance for individual proteins.”

Thus, *at best*, the art of crystallization is unpredictable even to those skilled in the art who may either perform the experiments by hand or who are assisted by automated robotics because it often times requires thousands of individual experiments in order to find the one or two conditions that are successful for a single protein. Even then, there is no guarantee. It is even a well known fact in the art that luck often times play a fortuitous role in obtaining successful crystallization conditions despite the extremely

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high skill level of those in the art (see Drenth, "Principles of Protein X-Ray Crystallography", 2<sup>nd</sup> Edition, 1999 Springer-Verlag New York Inc., Chapter 1, p. 19, 4<sup>th</sup> paragraph, lines 1-2). Furthermore, the prior art is of little assistance because while other antibodies have been crystallized, no anti-EGFR antibodies in any form (e.g. Fab fragments, single chain antibodies, etc.) have been successfully produced. Thus, when all things are considered and the Wands factors are treated on their merits, the claim is not enabled because a great deal of undue experimentation would be expected and necessary in order to practice the full scope of claimed invention.

Therefore, claims to all anti-EGFR antibody crystals, and the broad recitation of the method claims thereof, are not fully enabled beyond that described in Examples 2 and 3 for the whole murine humanized monoclonal antibody of Erbitux/MabC225/cetuximab.

Written Description:

17. Claims 1-3 and 6-18 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a broad genus of any crystal of anti-EGFR antibody crystals, and those in pharmaceutical compositions and methods of making thereof. While the structure and function of some a single species of said genera of anti-EGFR antibody crystals is disclosed in the specification, the common characteristics of the species that define said genera are not described. Furthermore, the genus of anti-EGFR antibodies

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is very broad and diverse and the single species of Erbitux/MabC225/cetuximab described in the specification in crystalline form is not representative of this entire genus of solid crystal anti-EGFR antibodies.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (*Enzo Biochem* 63 USPQ2d 1609 (CAFC 2002)).

The specification fully describes a single species of Erbitux/MabC225/cetuximab crystals that are produced by a batch method which produces crystals from slightly different conditions that fall within the instant genera of crystals. Examples 2 and 3 describe the precise antibody/protein concentration and the buffer which said antibody is in and the exact crystallization conditions which results in crystals. Example 2 used

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10 mM phosphate buffers at pH 8.0 and saturated ammonium sulfate in the same phosphate buffer to produce crystals whereas Example 3 used 10 mM citrate buffer at pH 5.5 and 50% ethanol in the same citrate buffer to produce crystals of Erbitux/MabC225/cetuximab. These two examples sufficiently and fully describe a single species of anti-EGFR antibody crystals. However, these species do not sufficiently describe the entire genus of anti-EGFR antibody crystals.

In general, for a species of crystal to be adequately described, the following must be adequately disclosed in the specification and the claims: (1) the composition of the crystal (exact structural features of all molecules in the crystal must be described, including the protein/antibody (preferably a SEQ ID NO of all included residues) and any molecule bound to it) (2) the exact protein concentration and buffer the protein/antibody is in, (3) the exact temperature, buffers, salts, additives used for crystallization and (4) the technique used to obtain the crystal (e.g. vapor diffusion, microbatch, liquid-liquid diffusion, etc). The Erbitux/MabC225/cetuximab crystal species noted above have adequately met this burden. However, the process of obtaining the crystals which is encompassed by the breadth of the claims is not described sufficiently. A singular chemical composition can crystallize differently based on the crystallization conditions and techniques used (see, for example, Applicants failed attempts in Example 8). For example, if a skilled artisan wants to crystallize Erbitux/MabC225/cetuximab for structural studies, then the crystallization technique, buffer considerations, temperatures, etc. are going to be very different than trying to crystallize a protein/antibody

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for therapeutic use because the overall objectives are so different and the quality of the crystals are important.

However, based on the instant the specification, the chemical composition, the process of obtaining anti-EGFR antibodies in the first place, along with the process of obtaining crystals thereof, which are encompassed by the breadth of the claims is unpredictable to one of skill in the art. One of skill in the art would be unable to predict the structure of other members of the genera by virtue of the instant disclosure. Therefore, claims drawn to the instant genera of anti-EGFR antibody crystals are also not adequately described and the single species of Erbitux/MabC225/cetuximab crystals which fall within the structurally and functionally diverse genus is not deemed representative to claim the entire broad genus of anti-EGFR antibody crystals.

### ***Claim Rejections - 35 USC § 102***

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. Claims 1-3, 6-10, 12-14 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Kussie et al. (WO 2006/009694). It is noted that the priority date of Kussie et al. falls between the foreign priority date and the effective filing date of the



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PCT. However, since Applicants have not provided an English translation of the foreign priority document so that the Examiner is apprised to the contents and thus benefit claim to this document, the instant rejection is made of record but might be overcome after providing the noted translated foreign priority document.

Kussie et al. teach co-crystals of cetuximab Fab fragments (wherein said cetuximab is monoclonal human/mouse chimera - see p. 2, paragraph 0007) in complex with the extracellular domain of EGFR. The crystals were produced by the vapor diffusion crystallization method wherein the protein in solution was slowly exchanged to a supersaturated state wherein crystal nucleation and growth occur upon return to a metastable state. 15% PEG3350, 250 mM ammonium sulfate, 100 mM imidazole and 10 mM cadmium chloride at pH 7.5 were used as the precipitating agent, also known as the reservoir solution or buffer (see paragraphs 0093 and 0094, pp. 25-26). Thus, Kussie et al. teach an anti-EGFR antibody in solid form, which also is in a form pharmaceutically acceptable solution/buffer at 11 mg/ml.

20. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Mahler et al. (US 2004/0170632 A1 – cited on IDS 05-26-2006). Mahler et al. teach a liquid formulation of cetuximab at 5 mg/ml (see claim 10). The limitation of claim 13 recites that the anti-EGFR antibody can be in soluble form. Thus, the teachings of Mahler et al. anticipate this claim.

***Conclusion***

21. No claim is allowed.
22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suzanne M. Noakes/  
Primary Examiner, Art Unit 1656  
08 June 2008